

"Bee Royale, Inc. does not claim that it, as a corporation, can raise the question of the constitutional provision of freedom from disclosure as applied to it. Its argument concedes that the corporation itself may not claim the Fifth Amendment. *United States v. White*, 322 U.S. 694 (1944); *Wilson v. United States*, 221 U.S. 361 (1911).

"The argument has a further basis, however. It says that answers by a corporation to interrogatories addressed to it must, obviously, be made by some human being on its behalf. Now if the corporate officer who gives the answers, on behalf of the corporation, states things that may involve criminal responsibility, he may find himself involved in a criminal prosecution, especially since liability of corporate officers under the food and drug act is one at peril and no mens rea is involved. See *United States v. Dotterweich*, 320 U.S. 377 (1943). But personal criminal liability was the very point involved in the *White* case, *supra*.

"This argument would present more possibilities for hardship if the questions were to be answered only by an officer who would be competent to testify on the corporation's behalf, as was the rule prior to the 1948 amendment. See 4 Moore, Federal Practice § 33.07 (2d ed. 1950). Under the amended rule the agent who answers on behalf of the corporation does not need to have personal knowledge. The corporation's attorney will do. 4 Moore, Federal Practice § 33.07 (2d ed. 1950).

"But we are getting into unnecessary difficulties here. The Fifth Amendment plea is a personal one and a corporation cannot take advantage of it. That is really all that is involved as this case came to the district court and as it comes to us. Accord: *United States v. 48 Jars etc.* — F. Supp. — (D.D.C. Nov. 14, 1958).

"The judgment of the district court will be affirmed."

**5984. Vitamin B<sub>12</sub> injection.** (F.D.C. No. 41285. S. No. 79-243 M.)

QUANTITY: 991 packaged vials at Brooklyn, N.Y.

SHIPPED: 11-13-57, from Chicago, Ill., by Hallmark Laboratories, Inc.

LABEL IN PART: (Vial) "10 cc Vial \* \* \* Vitamin B<sub>12</sub> Crystalline U.S.P. 1000 Micrograms per cc in Isotonic Sod. Chloride Soln. with 2% Benzyl Alcohol Intramuscular-Intravenous \* \* \* 051177."

RESULTS OF INVESTIGATION: Examination showed that each cubic centimeter of the article contained 995 micrograms of cyanocobalamin (vitamin B<sub>12</sub>), 8.96 milligrams of sodium chloride, and a substantial amount of unidentified dissolved material.

LIBELED: 12-18-57, E. Dist. N.Y.

CHARGE: 501(b)—when shipped, the quality and purity of the article fell below the standard for *cyanocobalamin injection* set forth in the United States Pharmacopeia since it contained a substantial amount of unidentified dissolved material which is not permitted by the standard as an ingredient of *cyanocobalamin injection*; and 505(a)—the article, because of the presence of unidentified dissolved material, was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to such drug.

DISPOSITION: 4-29-59. Consent—destruction.

#### DRUG FOR VETERINARY USE

**5985. Cardiobee 15 Injection and Pangamic Acid (B-15) capsules.** (F.D.C. No. 42313. S. Nos. 1-412 P, 2-316 P.)

QUANTITY: 584 cartoned vials of *Cardiobee 15 Injection* and 1 vial of *Pangamic Acid capsules* at Hialeah, Fla.

SHIPPED: Between 4-17-58 and 8-6-58, from San Francisco, Calif., by John Beard Memorial Foundation.

**LABEL IN PART:** (Vial and carton) "10 cc Multiple Dose Sterile Vial Cardiobee 15 Injection Each cc contains 100 mg. of Na-Glucono-di (N-Diisopropylamino) Acetate, Benzyl Alcohol 2% Physiological Saline Solution q.s. For Veterinary Use Only Dist. by Zirin Enterprises Hialeah, Florida" and (vial) "Blue \* \* \* Gold B-15 Capsules each capsule contains 50 mg. Pangamic Acid (Vitamin B-15) Na-Glucono-di (N-diisopropylamino) acetate."

**LIBELED:** 12-4-58, S. Dist. Fla.

**CHARGE:** 505(a)—the articles were new drugs which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to such drugs.

**DISPOSITION:** 8-4-59. Default—destruction.

**DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS**

**5986. Pituitary anterior solution.** (F.D.C. No. 42984. S. No. 28-499 P.)

**QUANTITY:** 75 ctnd. vials at Houston, Tex.

**SHIPPED:** 1-27-59, from Philadelphia, Pa., by Vitamix Corp.

**LABEL IN PART:** (Vial and ctn.) "30 cc. Multiple Dose Vial Vitopit \* \* \* Intramuscular Only \* \* \* Distributed by Coastal Medical Supply Co. Houston, Texas Each cc. Represents The Water Soluble Extraction of Dried Glands Derived From: Anterior Pituitary, Fresh Gland \* \* \* 10½ Grs. Ovarian Whole Gland, Fresh Gland \* \* \* 40 Grs. Procaine HCL \* \* \* 1% Chlorobutanol (Chloral Deriv.) 0.5% Contains No Recognized Therapeutically Active Ingredients. Indications: Non-Specific Protein Therapy."

**LIBELED:** 4-15-59, S. Dist. Tex.

**CHARGE:** 502(a)—when shipped, the label statement "Indications: Non-specific Protein Therapy" was false and misleading as applied to an article which is not an adequate and effective protein therapy treatment; and 502(f) (1)—the label of the article failed to bear adequate directions for use since no adequate directions could be written as the article was without therapeutic value.

**DISPOSITION:** 6-1-59. Default—destruction.

**5987. Nutri-Bio Food Supplement.** (F.D.C. No. 43216. S. No. 51-962 P.)

**INFORMATION FILED:** 8-5-59, Dist. Minn., against Gordon R. Cook, t/a Nutri-Bio Products, Brainerd, Minn.

**ALLEGED VIOLATION:** On 2-16-59, while the article was being held for sale by the defendant after shipment in interstate commerce, the defendant caused oral representations to be made in the course of a sales talk holding the article out as an effective treatment for various diseases, symptoms, and conditions as hereinafter described, which act resulted in the article being misbranded.

**LABEL IN PART:** (Ctn.) "NUTRI-BIO food supplement natural or organic VITAMINS AND MINERALS Suggested Daily Portions As a Dietary Supplement 364 Mineral Tablets 182 Vitamin Tablets."

**CHARGE:** 502(f) (1)—the labeling of the article failed to bear adequate directions for use in the treatment of the diseases, symptoms, and conditions for which the article was intended, namely, sinusitis, nervous indigestion, arthritis, swelling of joints, rheumatism, reducing, overeating, hunger, gaining weight, nervousness, nervous breakdown, inadequate assimilation of food, blood clot, cavities in teeth, diarrhea of infants, ulcers, stomach flu, lack of